510(k) SUMMARY (21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

The assigned 510(k) number is: _____

Premarket Notification [510(k)] Summary

A. General Information

Submitter's Name:	DANYANG COMED HEALTHCARE CO., LTD.
Address:	No. 3, Bei Er Huan Road 212300, Danyang City Jiangsu Province, P.R. China
Telephone:	86511-86963500
Fax Number:	86511-86963700
Contact Person:	William Sun
Date Prepared:	March 13, 2012

B. Device

Trade Name:	Comed K-Series Manual Wheelchair
Common Name:	Wheelchair
Classification Name:	Wheelchair, Mechanical
Product Code:	IOR
Class:	I
Regulation Number:	21 CFR 890.3850

C. Identification of Legally Marketed Predicate Device

Name:	Danyang HUAYI H035 Basic Wheelchair
Manufacture:	Danyang Huayi Medical Supply & Equipment, Co. Ltd.
K Number:	K080114
Date Cleared:	15 February 2008

D. Description of the Device

The Comed K-Series Manual Wheelchair is a user-propelled, manually operated folding wheelchair that is indicated for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and pocked dirt) that are free of large obstacles and inclines greater than 9 degrees. It consists of a mechanical steel frame and nylon upholstery. Designed to be lightweight and foldable, the model is approximately 18" wide, approximately 16" deep, has a weight capacity of 220lbs, and weighs approximately 42lbs.

E. Intended Use

Its intended use is to provide mobility to persons restricted to a sitting position.

F. **Conformance To Standards**

Both the new device and the predicate device were tested against the following non-clinical standards:

- ISO7176-1 ***Wheelchair: Determination of Static Stability***
- ISO7176-3 ***Wheelchair: Determination of Efficiency of Brakes***
- ISO7176-5 ***Determination of Overall Dimension, Mass, and Turning Space***
- ISO7176-7 ***Measurement of Seating and Wheel Dimensions***
- ISO7176-8 ***Wheelchair Requirement and Test Methods of for Static, Impact and Fatigue Strength,***
- ISO7176-11 ***Wheelchair: Test Dummies***
- ISO7176-13 ***Determination of Friction of Test Surface***
- ISO7176-15 ***Wheelchair: Requirements for Information Disclosure Documentation and Labeling***
- ISO7176-16 ***Wheelchair: Resistance to Ignition of Upholstered Parts- Requirement and Test Methods***.

The predicate and the new device meet all of the above named standards, indicating that the Comed K-Series Manual Wheelchair is as safe, as effective, and performs as well as the predicate device.

G. **Comparison of Technological Characteristics**

In comparison of technological characteristics, the new device is the same as the predicate device with respect to the frame material, footrests and leg rests, rear axles, wheels, upholstery, wheel locks, weight capacity and approximate total weight (with armrest). The Comed K-Series Manual Wheelchair is slightly larger than the predicate device, which is a design change that was made to make users of the wheelchair more comfortable. The difference in size of the new device does not raise new questions of safety and effectiveness.

H. **Conclusion of Substantial Equivalence**

Based on the comparison of intended use, design, materials, and performance, we conclude that the new device is substantially equivalent to the predicate device and that it raises no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DANYANG COMED HEALTHCARE CO., LTD.
% Rhonda Alexander, M.S, M.P.A
Senior Regulatory Specialist
144 Research Drive
Hampton, Virginia 23666

MAY 14 2012

Re: K120077
Trade/Device Name: COMED K-series Manual wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: April 19, 2012
Received: April 20, 2012

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **COMED K-series Manual wheelchair**

Indications For Use:

Its intended use is to provide mobility to persons restricted to a sitting position.

Prescription Use: ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120077